In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 03-355V
(to be published)

* *

PETER LOUTOS, II, *and* RAMONA LOUTOS, *as parents and natural guardians of P.A.L., III, a minor*,

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES ,

Respondent.

* *

Special Master Corcoran

Dated: December 9, 2016

Dismissal of Action; Autism; DTaP Vaccine; Statute of Limitations; Onset of Symptoms

Peter Loutos, II, and Ramona Loutos, Port St. Lucie, FL, *pro se* Petitioners.

Linda Renzi, U.S. Dep't of Justice, Washington, DC, for Respondent.

DECISION DISMISSING CLAIM AS UNTIMELY[1]

On February 19, 2003, Peter and Ramona Loutos, as parents and natural guardians of P.A.L., III, a minor ("P.A.L."), filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program" or "Program"),[2] alleging that P.A.L. incurred an encephalopathic injury as a result of vaccines he received in December 1999, later manifesting as

[1] Because this decision contains a reasoned explanation for my action in this case, it will be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, 44 U.S.C. § 3501 (2012). As provided by 42 U.S.C § 300aa-12(d)(4)(B), however, the parties may object to the decision's inclusion of certain kinds of confidential information. To do so, Vaccine Rule 18(b) permits each party fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the decision will be available to the public. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended, 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act.

autism or an unspecified severe neurologic injury with developmental impact similar to autism. ECF No. 1.

The matter had been set for an entitlement hearing to be held in June 2016, but in the process of filing pretrial briefs, Respondent requested dismissal of Petitioners' claim, alleging that it was untimely under the Vaccine Act's three-year statute of limitations. *See* Section 16(a)(2). I provided Petitioners an opportunity to modify their claim, based upon their representations that the claim could still be viable under the facts of the case, and that they would also offer revised expert reports to account for the change in allegations. Petitioners have since filed these reports, along with an amended petition – but all of these materials continue to rely on and reference the same facts pertaining to onset that Respondent persuasively argues render the claim time-barred. Having reviewed the new filings, as well as the parties' briefing on the limitations issue, I hereby **GRANT** Respondent's motion to dismiss.

Factual Background

This matter has been pending for more than thirteen years. The Loutoses originally filed a short form petition on February 19, 2003, as part of the Omnibus Autism Proceeding ("OAP").[3] ECF No. 1. That petition alleged that P.A.L. (born on September 3, 1998) suffered from autism spectrum disorder ("ASD") as a result of receiving the measles-mumps-rubella ("MMR") vaccine and/or thimerosal-containing vaccines before he was two years old. On August 25, 2011, and

[3] In the OAP, thousands of petitioners' claims that certain vaccines caused autism were joined for purposes of efficient resolution. A "Petitioners' Steering Committee" was formed by many attorneys who represent Vaccine Program petitioners, with about 180 attorneys participating. This group chose six "test" cases to represent the entire docket, with the understanding that the outcomes in these cases would be applied to cases with similar facts alleging similar theories. The first theory alleged that the measles portion of the MMR vaccine precipitated autism, or, in the alternative, that MMR plus thimerosal-containing vaccines caused autism, while the second theory alleged that the mercury contained in thimerosal-containing vaccines could affect an infant's brain, leading to autism.

The first theory was rejected in three test case decisions, all of which were subsequently affirmed. *See generally Cedillo v. Sec'y of Health & Human Servs.*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec'y of Health & Human Servs.*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 88 Fed. Cl. 473 (2009), *aff'd*, 605 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec'y of Health & Human Servs.*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 88 Fed. Cl. 706 (2009).

The second theory was similarly rejected. *Dwyer v. Sec'y of Health & Human Servs.*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec'y of Health & Human Servs.*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

Ultimately a total of 11 lengthy decisions by special masters, the judges of the U.S. Court of Federal Claims, and the panels of the U.S. Court of Appeals for the Federal Circuit unanimously rejected the test case petitioners' claims. These decisions found no persuasive evidence that the MMR vaccine or thimerosal-containing vaccines caused autism. The OAP proceedings concluded in 2010.

following the OAP's conclusion, Petitioners' prior counsel filed a status report indicating that Petitioners were going to proceed with their claim under a different theory - that P.A.L. suffered from an underlying mitochondrial disorder, and were in the process of obtaining the necessary expert and evidentiary support for it. ECF Nos. 22 and 23.

Since that time, the Loutoses have filed an amended petition which sets forth the most up-to-date recitation of their claim. *See* Amended Petition, dated November 23, 2016 (ECF No. 143) ("Amended Pet."). As the Amended Petition states, the Loutoses base their claim on two vaccines P.A.L. received at his 15-month well-child pediatric visit on December 17, 1999 – the Diphtheria-Tetanus-acellular Pertussis ("DTaP") and haemophilus influenza type b ("Hib") vaccines – although the claim as pled focuses on the DTaP vaccine. Amended Pet. at ¶¶ 4, 17-18. By March 2000, the Loutoses began expressing concerns to their pediatrician about P.A.L.'s development, which had become evident to them at the end of February 2000. *Id.* at ¶¶ 8-9. P.A.L. subsequently stopped talking and regressed in language, and by the fall of 2000 was diagnosed as having a chronic encephalopathy. *Id.* at ¶¶ 10-13.[4]

The Amended Petition differentiates between reactions the Loutoses first observed in P.A.L. after he received the DTaP vaccine and the manifestation of his later developmental regression and/or autism. Petitioners allege that P.A.L. experienced a fever and rash within days of the December 1999 vaccinations, which lasted into early January 2000 and which "set [P.A.L.] up for a severe brain injury." Amended Pet. at ¶ 5. They note that his reactions to the DTaP vaccine are similar to those reported to the Vaccine Adverse Event Reporting System ("VAERS") in other cases (although it does not appear from my review of the record that Petitioners ever filed such a report in this case, or any of the allegedly similar VAERS reports).[5] *Id.* at ¶¶ 6-7. At the same time,

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[4] P.A.L. received the encephalopathy diagnosis from Dr. Jeffrey Bradstreet, who first began treating P.A.L. in the fall of 2000. Amended Pet. at ¶ 13; Pet'rs' Ex. 14 at 52. Dr. Bradstreet was a practicing physician who specialized in children with autism spectrum disorder and attention deficit hyperactivity disorder, and who espoused the belief that there is a causal link between autism and the MMR vaccine (particularly due to what he alleged to be toxic amounts of mercury contained within the vaccine). *See, e.g., Hearing before the Committee on Government Reform*, June 19, 2002, Serial No. 107-121, available at https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg82358/html/CHRG-107hhrg82358.htm (last visited on Dec. 6, 2016). But treatments promoted by Dr. Bradstreet have not been proven effective, and even termed dangerous. Trine Tsouderos and Patricia Callahan, *Risky Alternative Therapies for Autism Have Little Basis in Science*, Chicago Tribune, Nov. 22, 2009 (chelation therapy and hyperbaric chamber therapy sessions are unproven and potentially dangerous). Dr. Bradstreet committed suicide on June 19, 2015, shortly after his clinic was raided by state and federal authorities. Michael E. Miller, *Anti-Vaccine Doctor behind 'Dangerous' Autism Therapy Found Dead. Family Cries Foul*, Washington Post, June 29, 2015, available at https://www.washingtonpost.com/news/morning-mix/wp/2015/06/29/anti-vaccine-doctor-behind-dangerous-autism-therapy-found-dead-family-cries-foul/ (last visited Dec. 6, 2016).

[5] VAERS is a national vaccine safety surveillance program co-sponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration, and allows individuals who believe they may have experienced a vaccine reaction to make a report of the incident. *See* https://vaers.hhs.gov/index (last visited Dec. 6, 2016). Although in this case Petitioners appear to cite these VAERS reports principally to corroborate the timing of their allegations, the value of a specific VAERS report as evidence in proving causation in a Vaccine Program case is extremely limited. *Tompkins v. Sec'y of Health and Human Servs.*, No. 10-261V, 2013 WL 3498652, at *16 (Fed. Cl. Spec. Mstr. June

however, Petitioners also take pains to allege that P.A.L.'s "severe brain injury" became apparent only by late February 2000 or early March 2000. *Id.* at ¶¶ 5, 8-9. Thus, they formally propose that the onset of P.A.L.'s injury was "delayed" to late February or early March 2000. *Id.* at ¶ 16.[6]

Procedural History

Petitioners began filing medical records in support of their claim after its initiation in 2003. *See, e.g.*, ECF Nos. 12, 15, and 19. The case's progress was largely stayed during the pendency of the OAP hearings (and indeed, no work at all was performed on this case between 2004 and 2007). On September 7, 2011, Petitioners' counsel withdrew, and for the past five years Petitioners have been *pro se* litigants. There were numerous subsequent delays in the case.

In 2014, the Loutoses filed two expert reports supporting their causation theory – one from Janet Kern, PhD (Pet'rs' Ex. 52), and a second from Lisa Rankin, MD (one of P.A.L.'s treating physicians) (Pet'rs' Ex. 53). ECF No. 82. Both reports identified December 1999 as the start of P.A.L.'s reaction to the DTaP vaccine. Thus, Dr. Kern (a neuroscientist) opined in her report that P.A.L.'s reaction manifested within 48 hours, and that his symptoms subsequently progressed and worsened to include brain damage, resulting in a subsequent diagnosis of encephalopathy. ECF No. 82-1 at 5-6. She further expressed the view that P.A.L showed a progressive and sequential pattern of regression into ASD as a result of these December 1999 vaccines, and that the encephalopathy was a factor in his ASD (along with his alleged mitochondrial dysfunction).

Dr. Rankin's expert report similarly opined in favor of Petitioners' causation theory based on the same conception of onset occurring in December 1999. Dr. Rankin proposed that P.A.L.'s symptoms began within 48 hours of his receipt of the DTaP vaccine, "and continued from that point on progressed [sic] to the point of having multiple office visits over the next three months leading up to his 18 month check [March 2000]." ECF No. 82-2 at 1. Thus, as of 2015, both of Petitioners' experts had embraced causation theories rooted in the factual assumption that P.A.L.'s reaction to the vaccines he had received began in December 1999 – first the neurologic injury of encephalopathy, proximately followed by developmental problems that later manifested.

The case was assigned to me in early 2015. Over the next several months, Petitioners briefed, and I decided, a long-pending interim fees request (*see* Decision, dated December 18,

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21, 2013) ("VAERS is a stocked pond," and its individual reports lack scientific reliability), *motion for review den'd*, 117 Fed. Cl. 713 (2014).

[6] Petitioners also have alleged that P.A.L. had a number of underlying conditions that the DTaP vaccine likely exacerbated, including (a) mitochondrial dysfunction, (b) deficient glutathione levels, (c) and an MTHFR genetic deficiency, all of which made him more susceptible to a neurologic reaction to the vaccine. Amended Pet. at ¶¶ 14, 17. They have not, however, formally alleged a significant aggravation claim in their Amended Petition – although, for purposes of my analysis, their claim would still be time-barred since the Petitioners rely on December 1999 and January 2000 reactions as part of their claim that P.A.L.'s underlying conditions were impacted by the DTaP vaccine.

2015 (ECF No. 120)). More importantly, the matter was finally set for hearing on June 9, 2016, and a pretrial order was issued for the filing of prehearing memoranda and trial-related materials. Scheduling Order, dated December 17, 2015 (ECF No. 119).

Statute of Limitations Issue

The timeliness of Petitioners' claim was first raised with me during pretrial briefing last spring. However, the matter also came up earlier in the case's history (although it was somewhat forgotten with the passage of time).[7]

In July 2008, and while the OAP was pending, Respondent filed a "statement" regarding the propriety of the matter's inclusion in the OAP. ECF No. 13. In it, Respondent stated that she could not, based on the existing record, determine whether the claim was timely. Certain medical records filed in support of the claim suggested that onset of a reaction purportedly resulting in P.A.L.'s autism and/or developmental problems had occurred between late-December 1999 and February 2000. Because this matter had been filed on February 19, 2003, however, the claim would only be timely if onset of P.A.L.'s symptoms occurred no earlier than February 19, 2000.

In response to this statement, the special master then-presiding over this case issued an order requiring Petitioners (who were at this time still represented by counsel) to address the matter of the claim's timeliness in a written filing. Order, dated July 28, 2008 (ECF No. 14). Petitioners filed their response on August 28, 2008 (ECF No. 16). That response asserted that as of a March 6, 2000 well-child pediatric visit, P.A.L. was "developing age appropriately . . . and not manifesting any signs or symptoms or any significant aggravation of a vaccine injury." ECF No. 16 at 3. They also alleged that the earliest symptom or manifestation of onset of P.A.L.'s injury occurred no earlier than September 5, 2000, because hospital records revealed that he first began receiving assessment and treatment for developmental problems at that time. *Id.* If so, Petitioners' claim would be timely, since onset would have been less than three years from the date of filing.

In January 2009 (and in response to a request from the special master to address the issue further (*see* Order, dated September 29, 2008 (ECF No. 17)), Respondent filed a supplemental statement on the limitations question. Supplemental Statement, dated January 16, 2009 (ECF No. 18) ("Supplemental Statement"). The Supplemental Statement reiterated Respondent's view that the claim's timeliness remained an unresolved matter, since there was evidence (for example,

[7] The inordinate delay in resolving this case is regrettable. Based on review of the entire file, however, I cannot attribute it to any one factor or party. Rather, a combination of (a) the impact of waiting on the OAP's conclusion, (b) Petitioners subsequently becoming *pro se* litigants, burdening them with the challenge of prosecuting a complex action, and (c) numerous subsequent requests by the Loutoses for extensions of time (*see, e.g.*, Motion for Suspension of Proceeding, dated January 15, 2015 (ECF No. 97)) all worked in concert to impede the speedy adjudication of Petitioners' claim. In addition, the matter was presided over by three special masters, with it only assigned to me in early 2015. *See* Transfer Order, dated February 5, 2015 (ECF No. 100).

statements made by the Loutoses to treaters) that P.A.L.'s developmental problems manifested as early as 15 months of age, or in December 1999. Supplemental Statement at 3. As a result, Respondent took "no position regarding the timeliness of the claim," but reserved the right to raise "jurisdictional concerns" later, once more of the record had been filed. *Id.* at 4 n.4.

Pre-hearing briefing this past winter in preparation for the June 2016 entitlement hearing brought the limitations issue back into contention. Petitioners' prehearing submissions, dated March 24, 2016 (ECF No. 125), placed onset of the encephalopathy that led to P.A.L's regression and subsequent developmental problems as having occurred on (or shortly before) December 1999 (and Petitioners' experts relied on that same date of onset). *See, e.g.,* Prehearing Submissions at 2, 6 ("by the time his regression began at 15 months, . . ."), and 8. The Loutoses' causation theory proposed that P.A.L. suffered a series of progressive reactions to the DTaP vaccine beginning around the time he received it at 15 months of age (December 1999), ultimately culminating in a severe neurologic injury as corroborated by the fall 2000 encephalopathy diagnosis. *Id.* at 3-5.

Respondent thereafter requested a status conference in order to discuss whether Petitioners' factual allegations about the onset of P.A.L.'s symptoms rendered the claim time-barred, and I scheduled one for April 14, 2016. After it, I issued a Scheduling Order (Order, dated April 15, 2016 (ECF No. 128)) directing Respondent to address the limitations issue further in her pending prehearing submission.

Respondent filed her pretrial submission on April 25, 2016 (ECF No. 129), including within it a motion to dismiss ("Motion").[8] She recounted the law relevant to the Vaccine Act's limitations period, stressing that a claim begins to run from the "date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury," as would be medically recognized. Motion at 8, *citing Cloer v. Sec'y of Health & Human Servs.,* 654 F.3d 1322, 1335 (Fed. Cir. 2011). She also observed that there is no "discovery rule" under the Vaccine Act that would otherwise extend the limitations period to when Petitioners knew, or should have known, of their claim. Motion at 9. Because the facts relevant to Petitioners' claim squarely identified onset of P.A.L.'s alleged reaction as having occurred as early as December 1999, the case had been filed two months late. *Id.* at 9-11.

After reviewing Respondent's Motion, I held another status conference on May 4, 2016. I expressed my concern to Petitioners that, based on the recent filings, it was evident that their claim was not procedurally viable if they intended to argue at hearing that onset of P.A.L.'s symptoms

[8] I had also asked Respondent to explain why the limitations issue was only being raised on the eve of trial, rather than earlier in the case's lengthy history, since it was potentially fatal to the claim and therefore should have been brought to the attention of the Court far sooner. She did so briefly in her pretrial submission, recounting some of the prior procedural history discussed above from 2008. Motion at 1-2. While it would have been preferable for Respondent to press this issue more forcefully earlier in the case, the procedural history shows that the question of the limitations issue *was in fact raised,* albeit without clear resolution, in 2008 and 2009.

began in December 1999. However (and based in particular on the 2008 filings relevant to the limitations question that had identified September 2000 as the onset time), it was conceivable that the claim was timely, assuming Petitioners could obtain revised expert opinions consistent with a revised fact pattern (and of course assuming the evidence supported such allegations as well). Therefore, and in the interests of providing Petitioners an additional chance to make their case, I cancelled the June 2016 hearing. Scheduling Order, dated May 9, 2016 (ECF No. 131) at 1. I ordered Petitioners to respond substantively to Respondent's Motion as well. Order at 2.

Petitioners filed their response to the motion on June 8, 2016 (ECF No. 132) ("Opp."). They characterized what appeared to be evidence of onset of P.A.L.'s reaction to the December 1999 vaccines as merely establishing "a potential underlying intolerance," but that his real onset occurred after his March 2000 well-child visit (in which case their claim would not be time-barred). Opp. at 5. They stressed their identity as *pro se* litigants as possibly contributing to confusion on Respondent's part about the nature of their claim. *Id.* at 6 ("[a]t no point were Petitioners trying to establish that the symptoms following the December 17, 1999 visit were *the* . . . result and *only* cause" of the alleged injury) (emphasis in original). They also proposed, without citation to evidence, that P.A.L. had received another vaccine at the March 2000 well-child visit (*Id.* at 2), although that allegation was never corroborated by the record and appears to have been dropped, as it is not mentioned in the Amended Petition.[9]

I held yet another status conference on August 3, 2016. After reviewing the parties' filings on the limitations question, and hearing from them during the conference, I provided Petitioners with the opportunity to amend their petition and supporting expert reports (assuming the experts could do so in good faith) to be consistent with their allegations of onset occurring after February 2000, and set deadlines for so doing. Order, dated August 4, 2016 (ECF No. 136). However, I also stated that Respondent had persuasively established that Petitioners could not advance a claim involving onset any earlier than February 19, 2000, and that I would otherwise defer ruling formally on the Motion to Dismiss until I had reviewed what Petitioners filed. *Id.* at 2.

Petitioners delayed in filing their required amended petition and expert reports until November. *See* Dr. Kern's Amended Report, filed November 28, 2016 (ECF No. 144-1) ("Amended Kern Rep."); Dr. Rankins's Amended Opinion Letter, dated November 29, 2016 (ECF No. 145-1); and Amended Pet. But these documents repeat the same fact allegations of vaccine reactions in December 1999 that first motivated Respondent to request dismissal. *See* Amended Pet. at 2 (¶¶ 5-7). The revised expert reports similarly continue to rely on, or even invoke outright, P.A.L.'s alleged December 1999 initial symptoms. Thus, Dr. Kern references again the same series of immediate post-vaccination symptoms from December 1999 as part of the overall causation

[9] Respondent for her part has found no evidence in the record that any March 2000 vaccine was ever administered to P.A.L. *See* August 22, 2016 Status Report (ECF No. 137).

chain that begins with the December 17th vaccinations. *See* Amended Kern Rep. at 23 *("[a]s time progressed his symptoms were growing in number and intensity*, such that by the end of February, 2000 (approximately 9 weeks after vaccination), he was showing signs of neurological loss") (emphasis added). Dr. Rankin's updated opinion letter does the same. *See* ECF No. 145-1 at 1.

Analysis

I. Petitioners' Claim is Time-Barred.

The statute of limitations prescribed by the Vaccine Act is three years, or thirty-six months. Section 16(a)(2). Thus, the period in which to bring a Program claim terminates "after the expiration of 36 months after the date of the occurrence of the first symptom of manifestation of onset or of the significant aggravation of such injury." *Id.* The statute of limitations begins to run from the manifestation of the first objectively cognizable symptom, whether or not that symptom is sufficient for diagnosis. *Carson v. Sec'y of Health & Human Servs.*, 727 F.3d 1365, 1369 (Fed. Cir. 2013). Special masters have appropriately dismissed cases that were filed outside the limitations period, even by a single day or two. *See, e.g., Spohn v. Sec'y of Dep't of Health & Human Servs.*, No. 95-0460V, 1996 WL 532610 (Fed. Cl. Spec. Mstr. Sept. 5, 1996) (dismissing case filed one day beyond thirty-six-month limitations period), *mot. for review denied*, (Fed. Cl. Jan. 10, 1997), *aff'd*, 132 F.3d 52 (Fed. Cir. 1997).

I invited Petitioners to attempt to correct their claim because they maintained it was possible to do so. I also took note of the fact that in 2008, Petitioners had asserted that onset of P.A.L.'s symptoms did not actually begin until September 2000. However, as their recently-filed revised expert reports, amended petition, and brief reveal, this is not the case. All of these documents continue to rely on allegations about PAL's initial December 1999 reactions as integral to their overall claim, and record documents corroborate the pediatric appointments at which time the reactions allegedly occurred. *See* Pet'rs' Ex. 32 at 16-17; Ex. 8 at 1 (showing pediatric visits from December 1999 and January 2000). Thus, Respondent's objections about the timeliness of the claim herein remain more than valid.

Petitioners have attempted to differentiate the earlier facts suggesting a reaction to the DTaP vaccine from later-documented instances of PAL's developmental problems, characterizing the former as evidencing vaccine "intolerance" that is somehow distinguishable from onset of his outward developmental and/or autism symptoms. But the law on this is matter is firm and persuasive – the first sign or related symptom constitutes onset, even if that sign is not *recognized* as such. *Carson,* 727 F.3d at 1369.

The nature of the claim at issue bears on resolution of the limitations question. This is not a case in which Petitioners are arguing that onset was the first manifestation of P.A.L.'s *autism*,

whether diagnosed or simply observed (and persuasive law suggests it is the latter that triggers a Vaccine Program claimant's claim). *See, e.g., White v. Sec'y of Health & Human Servs.*, No. 04-337V, 2011 WL 6176064, at *10-11 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (in claim alleging autism as injury, definitive diagnosis or health care provider opinion is not required to trigger running of limitations period). Rather, the Loutoses argue that an encephalopathy was triggered by P.A.L.'s DTaP vaccination (as evidenced in part by the symptoms he displayed not long after the vaccination), and that in turn the neurologic injury caused by the encephalopathy resulted in his developmental problems and/or autism. Amended Pet. at 3 ¶ 18 (P.A.L.'s injuries are "due to the encephalopathy caused by the DTaP vaccine administered to him on December 17, 1999").

An alleged encephalopathy can be the basis for a Table or Non-Table claim. However, the Table's precise definition of the term "simply does not encompass every type of brain dysfunction to which the broader meaning of 'encephalopathy' applies." *Wright v. Sec'y of Health & Human Servs.*, No. 12-423V, 2015 WL 6665600, at *6 (Fed. Cl. Spec. Mstr. Sept. 21, 2015); *Fester v. Sec'y of Health & Human Servs.*, No. 10-243V, 2013 WL 5367670, at *21, n. 5 (Fed. Cl. Spec. Mstr. Aug. 27, 2013). Thus, as noted by former Chief Special Master Vowell, the term encephalopathy, "as commonly used in the medical community, encompasses a much broader class of injuries than the more stringent definition of acute encephalopathy found in the QAI [qualifications and aids to interpretation]." *Wright*, 2015 WL 6665600, at *5 (*citing Waddell v. Sec'y of Health & Human Servs.*, No. 10–316V, 2012 WL 4829291, at *6 (Fed. Cl. Spec. Mstr. Sept. 19, 2012)).

Petitioners' amended petition does not appear to assert a Table encephalopathy claim,[10] and therefore more kinds of evidence can be considered in determining if one occurred. *See, e.g., Miller v. Sec'y of Health & Human Servs.*, No. 02–235V, 2015 WL 5456093, at *23 (Fed. Cl. Spec. Mstr. Aug. 18, 2015) (quoting Respondent's expert in that matter as defining encephalopathy to mean generally that "there's something wrong with the brain"). It does not matter how severe the initial reaction was. *Smith v. Sec'y of Health & Human Servs.*, No. 02-93V, 2006 WL 5610517, at *5 (Fed. Cl. Spec. Mstr. July 21, 2006) ("the Vaccine Act does not distinguish between subtle and pronounced symptoms for determining the point of onset"), *mot. for review den'd*, 2006 WL 5624674 (Fed. Cl. Nov. 16, 2006).

Here, that evidence is found in P.A.L.'s purported reaction to the DTaP vaccine, within 48 hours of its administration, as evidenced by his fever and reported reactions in the days and weeks immediately after he received the DTaP vaccine. Other petitioners, like the Loutoses, have similarly relied on evidence of fever or other initial reaction to a vaccination to demonstrate an underlying encephalopathic process, later manifesting in autism or other developmental problems.

[10] Thus, the amended petition references only a "chronic encephalopathy" as the product of P.A.L.'s DTaP vaccination – even though a Table encephalopathy requires proof of *both* an acute and chronic encephalopathy. 42 C.F.R. § 100.3(b)(2).

See, e.g., Murphy v. Sec'y of Health & Human Servs., No. 05-1063V, 2016 WL 3034047, at *31-33 (Fed. Cl. Spec. Mstr. Apr. 25, 2016) (no evidence of immediate reaction to vaccination sufficient to find encephalopathy in non-Table case), *mot. for review den'd*, No. 05-1063V (Fed. Cl. Aug. 15, 2016), *appeal docketed*, No. 2017-1047 (Fed. Cir. Oct. 14, 2016); *R.V. v. Sec'y of Health & Human Servs.*, No. 08-504V, 2016 WL 3882519 (Fed. Cl. Spec. Mstr. Feb. 19, 2016), *mot. for review den'd*, 127 Fed. Cl. 136 (Fed. Cl. July 1, 2016), *appeal dismissed,* No. 16-2400 (Fed. Cir. Oct. 26, 2016).

It is thus common for claimants asserting that a vaccine precipitated an encephalopathy that in turn manifested developmental problems and/or ASD symptoms to rely on facts relating to a purported initial reaction to the vaccine to prove the "start" of the encephalopathy – to show that some underlying, immunologic-related reaction was occurring that injured a child's brain. Based upon my review of Petitioners' recent filings and the record as well, it is evident that Petitioners' claim relies on P.A.L. experiencing a reaction to the DTaP vaccine in December 1999 and January 2000. *See, e.g.,* Pet'rs' Ex. 8 at 1 (purported January 2000 reaction). There can be no doubt that Petitioners allege that these occurrences relate to their claim – they reiterated them even after being put on precise notice of Respondent's limitations objections.

Petitioners unpersuasively object that they were not aware that P.A.L.'s earliest manifestations of his purported injury were vaccine-related, and thus were not cognizant of the existence of their claim until after February 2000. In so doing, they effectively invoke the "discovery rule," under which a "statute of limitations does not begin to run until an injured person *knew or should have known* that a vaccine had the ability to cause the injury from which she suffered." *Johnston v. Sec'y of Health & Human Servs.*, No. 11–796, 2013 WL 664709, at *4 (Fed. Cl. Spec. Mstr. Jan. 31, 2013) (emphasis added). But as Respondent's Motion observes, the discovery rule does not apply to Vaccine Act cases. *Cloer,* 654 F.3d at 1339. So even though the Loutoses may not have recognized that time began to run on their claim before P.A.L. openly exhibited his developmental problems, their claim as articulated over the past several years clearly is based on symptoms that began more than three years prior to the case's filing.

The Federal Circuit has held that the doctrine of equitable tolling can apply to Vaccine Act claims in limited circumstances. *Cloer,* 654 F.3d at 1340-41. These limited circumstances have been enumerated to include fraud and duress, but not a lack of awareness on a petitioner's part that she might have an actionable claim. *Id.* at 1344-45 (unawareness of a causal link between the injury and vaccination was insufficient to justify invocation of equitable tolling). None of the relevant circumstances that would permit tolling have been shown by Petitioners to apply herein, however.

II. Petitioners' Claim Would Likely Not Succeed Even if it Were Not Time-Barred.

I am resolving Petitioners' claim on the basis of a procedural deficiency rather than its underlying merits. However, my review of the medical records suggests that the claim would not likely have succeeded even if I had ignored its evident untimeliness and permitted it to go to hearing. The expert reports offered in support of the theories herein are not especially persuasive,[11] and the medical records do not contain any treater views contemporaneous with the December DTaP vaccination supporting the conclusion that the vaccine was ever linked to P.A.L.'s purported reaction or subsequent developmental problems.

Moreover, the nature of the claim at issue also bears on its merits. Since completion of the OAP, no petitioner asserting a non-Table claim for autism injuries purportedly related to a vaccine (and based on a theory not adjudicated in the OAP) has ever succeeded. *Hardy v. Sec'y of Health & Human Servs.*, No. 08-108V, 2015 WL 7732603, at *4-5 (Fed. Cl. Spec. Mstr. Nov. 3, 2015) (referencing eleven autism claims unsuccessfully tried, plus six that were rejected (over the petitioners' objections) without trial). Many such cases have involved claims that a preceding encephalopathy precipitated a developmental injury. *See, e.g., R.V.*, 2016 WL 3882519, at *35-36 (discussing kinds of proof necessary to establish encephalopathy that were lacking); *Lehner v. Sec'y of Health & Human Servs.*, No. 08-554V, 2015 WL 5443461 (Fed. Cl. Spec. Mstr. July 22, 2015) (petitioners failed to demonstrate that flu vaccine resulted in autoimmune encephalitis).[12] Nor have any petitioners been able to show, based on after-the-fact treater views, that a child even possessed a mitochondrial disease sufficient to experience a severe vaccine interaction resulting in autism or a developmental problem. *R.V.*, 2016 WL 3882519, at *33-35; *see also Miller*, 2015

[11] For example, Dr. Kern's Amended Report references the concept of "delayed encephalopathy" as allowing for the possibility that P.A.L. could have experienced an initial insult from the DTaP vaccine, but that his symptoms would be slow to manifest. Amended Kern Rep. at 9-11. But this theory still relies on the existence of an "initial acute phase" (*Id.* at 9) – meaning that there would have to be some evidence of a reaction closer in time to the vaccination, which in turn would (again) render the claim time-barred given the facts of this case. In addition, none of Dr. Kern's examples involve vaccine-mediated injuries, but instead involve disparate occurrences like carbon monoxide poisoning or hypoxia (oxygen deficiencies), where the impact of the insulting event is less disputed. To show that a DTaP vaccine could have the same impact, Dr. Kern relies on studies involving pertussis toxin (*Id.* at 11-13) – even though DTaP is comprised of the inactivated toxoid only, which lacks the same capacity to injure because it contains no more than residue amounts of the toxin. *Murphy*, 2016 WL 3034047, at *12 (acellular version of vaccine involves inactivated form of pertussis toxin).

[12] The parents of a vaccinated child have, on only one occasion, successfully established a Table injury – an encephalopathy – after vaccination that resulted in an autistic-like developmental regression. *See, e.g., Wright*, 2015 WL 6665600. In *Wright*, the petitioners met the Table criteria for an "acute encephalopathy" following vaccination by establishing by preponderant evidence that the vaccinated child experienced a seizure followed by loss of consciousness shortly after receipt of pertussis-containing vaccine; the severe reaction lasted for more than 24 hours, with resulting demonstrable significant changes in behavior temporally close to the time of vaccine administration. But the special master responsible for that decision (former Chief Special Master Vowell) explicitly noted in her decision that petitioners would *not* have been able to establish entitlement under their non-Table claim, because their expert presented a causation opinion that she found "absurd and biologically impossible." *Wright*, 2015 WL 6665600, at *2.

WL 5456093 (petitioners failed to demonstrate that several childhood vaccines aggravated underlying mitochondrial disease/dysfunction).[13]

CONCLUSION

It is unfortunate that so much time was devoted to a claim that might have been identified as untimely years ago. But the issue is now squarely before me – and Petitioners have failed to remedy this core deficiency in their claim. It is, moreover, a deficiency of which they were first placed on notice eight years ago, and one that I have attempted to provide them a reasonable opportunity to cure. They have not done so, and although I am cognizant of the Vaccine Program's remedial character (and the concomitant policy goal of allowing claimants – especially pro se litigants – a fair chance to prove their claims), such considerations do not override the Act's limitations provisions where they are applicable.

Accordingly, and for the reasons stated above, I hereby **DISMISS** this matter.

IT IS SO ORDERED.

Brian H. Corcoran
Special Master

[13] In a single case – *Paluck v. Sec'y of Health & Human Servs.*, 113 Fed. Cl. 210 (2013), *aff'd,* 786 F.3d 1373 (Fed. Cir. 2015) – a petitioner whom the parties *agreed* (or at least, where Respondent did not dispute) had a preexisting mitochondrial disease was successful in establishing (in a non-Table claim) that certain vaccines significantly aggravated that disease, resulting in developmental and other neurodegenerative injuries. That fact pattern is distinguishable from the present circumstances, in which Petitioners would need to prove that P.A.L. had such a condition – and in which they would, moreover, attempt to do so by relying on after-the-fact testing and expert opinions not contemporaneous to the vaccination. *See, e.g., Anderson v. Sec'y of Health & Human Servs.*, No. 02-1314V, slip op. at 35-36 (Fed. Cl. Spec. Mstr. Nov. 1, 2016) (noting the unpersuasive nature of after-the-fact testing results that revealed a possible mitochondrial disorder when those tests were not contemporaneous with when petitioner would have experienced the purported vaccine reaction), *appeal docketed,* Dec. 1, 2016 (Fed. Cl. 2016).